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**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

U.S. DISTRICT COURT
DISTRICT OF MASS.

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESAL PRICE
LITIGATION

MDL No. 1456

CIVIL ACTION: 01-CV-12257-PBS

THIS DOCUMENT RELATES TO
ALL CLASS ACTIONS

Judge Patti B. Saris

**REPLY MEMORANDUM IN RESPONSE TO DEFENDANTS' RESPONSE
TO NOTICE OF FILING OF MODIFIED AMENDED MASTER
CONSOLIDATED CLASS ACTION COMPLAINT**

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Plaintiffs submit this memorandum in response to Defendants' Response to the Notice of Filing of Modified Amended Master Consolidated Class Action Complaint.

I. INTRODUCTION

Defendants, represented by over fifty different law firms, employing hundreds of lawyers, having had a protracted period to respond to the AMCC, raised for the first time various standing issues at the oral argument on the motion to dismiss. Now, ignoring the allegations of the complaint, or misstating them completely, defendants again assert these new founded standing arguments and make additional standing arguments not presented at the hearing. None of these arguments withstand even slight scrutiny, and some are based upon outright distortions of the AMCC.

First, during the argument, plaintiffs' counsel were baffled by defendants' argument as to a lack of standing to assert the claims in Count I, which defense counsel claimed was limited to Part B covered drugs. This bafflement was reflected in a response to a question by the Court on the scope of Count I where counsel indicated that "I do want to think about it." Tr. at 54. The reason for that desire for reflection was puzzlement as to why defense counsel was insisting that Count I was limited to Part B drugs. Count I is not limited to Part B covered drugs. Even before the filing of the modified AMCC Count I covered all drugs in Appendix A that were sold based upon inflated AWP outside of the PBM context. As explained below, several of the plaintiffs have standing to assert such claims. As explained in Plaintiffs' Notice of Filing of Modified Amended Master Consolidated Class Action Complaint ("Notice"), defendants' argument in this regard is based on a typographical error in the heading of Count I and not the actual allegations of the complaint, an error that would have been corrected if defendants had simply made inquiry before the argument. The modified complaint corrects this error and renders this entire argument spurious.

Not only do defendants predicate their entire argument on an obvious typographical error in the heading of AMCC Count I, defendants then use this error as a basis to claim that the consumer claims in Count IV should also be limited to Part B covered drugs, despite the fact that consumer claims were always brought on behalf of a class of all end payors who paid for any drug identified in Appendix A. The claims in Count IV contained no typographical error and were never limited to Part B drugs. (*See* AMCC ¶ 595 defining class and ¶ 685 of Count IV.) Thus, defendants' argument as to these claims is simply an attempt to confuse the Court in the hopes that this confusion would lead to a dismissal of this claim.

As to the PBMs, defendants' argument is also without merit and is predicated on what defendants admit is incomplete "discovery," rather than on the controlling allegations of the complaint. Defendants claim that this minimal discovery entitles defendants to a ruling that "all claims in the AMCC related to payments through PBMs should be dismissed except for drugs on which PFT and Man-U made payments based on contracts with Express Scripts." Defs. Mem. at Conclusion. Yet the AMCC alleges, for example, that other plaintiffs such as plaintiff UFCW "from December 2000 to the present, UFCW contracted with a PBM" and that the contract provides that its drugs are priced "at AWP-13." ¶ 29. Thus, defendants' motion not only quarrels with the factual allegations of the complaint, it completely and without explanation ignores these controlling allegations.

Each of the union plaintiffs alleges what the Court requested, that the plaintiffs identify the nature of the existence of a contractual relationship with a PBM and a contractual tie to payment based upon AWP. Having realized that plaintiffs satisfy this requirement, defendants add new ones, namely, that the identity of each PBM that a plaintiff contracted with must be alleged in the AMCC. This new demand is the same tactic followed in other instances, where after the AMCC was filed,

defendants demanded a host of new pleading requirements they had not demanded previously. Many of the plaintiffs dealt with different PBMs or their predecessors over time and consistent with notice pleading, plaintiffs did not identify each and every PBM relationship, but did allege generally the existence of a PBM contractual relationship and the relationship in its drug payments to AWP. This is sufficient. However, defendants now claim for the first time that if plaintiffs did not utilize the services of one of the PBMs, then all transactions involving that PBM enterprise are not within the scope of the AMCC. Even if such a pleading requirement exists, this argument also fails as a matter of law. All plaintiffs have been injured by the PBM enterprises irrespective of dealings with a specific PBM. The AMCC has as one of its core allegations that the heart of the AWP scheme was to establish AWP as a benchmark for reimbursement of all AWPID drugs. The AMCC alleges that all of the PBM enterprises contributed to establishing AWP as an industry-wide benchmark. If any of the major PBMs did not agree to participate in using AWP and inflated AWP as a benchmark, then the entire process would collapse as purchasers would deal with the PBM reimbursing at the lower price as opposed to the inflated AWP. As a result of the multiple PBM enterprises covering over 85% of the PBM marketplace, all plaintiffs were injured by the ability of defendants and the PBMs to utilize the inflated AWP system as a benchmark for reimbursement and by their overpayment based on inflated AWP. This establishes RICO standing, namely that the conduct of the defendants through the operation of the PBM enterprises caused injury. Defendants' latest request for dismissal should be denied.

II. PROCEDURAL HISTORY

Count I of the Master Complaint was titled “Against Defendant Drug Manufacturers For Unlawful Conduct Associated with Medicare Part B Covered Drugs.” It was asserted by the Class I representatives on behalf of the following class:

Class I: The Medicare Part B Co-Pay Class

All persons or entities who, ... paid for the purchase of a prescription drug ... which payment constituted a contribution toward the Medicare Part B co-payment.

See MCC ¶ 333, and ¶ 344 identifying this class as the class bringing Count I.

The AMCC alleged different classes than the Part B co-pay class asserted in the MCC. The AMCC did not define the classes based upon Part B coverage in recognition of the fact that the AWP scheme was not limited to Part B drugs, but covered a broad range of drugs, Part B covered and non-Part B covered. Thus, the AMCC defines the class as follows:

595. Plaintiffs bring this action pursuant to Rule 23 of the Federal Rules of Civil Procedure, on behalf of themselves and two Classes comprised of:

AWP Payor Class:

All persons or entities who, for purposes other than resale and during the Class Period, paid any portion of the purchase for a prescription drug manufactured by a Defendant Drug Manufacturer (as identified in Appendix A) at a price calculated by reference to the published AWP during the Class Period.

Sub-Class: The PBM Third-Party Payor Class:

All Third-Party Payors that, during the Class Period, contracted with a PBM to provide to its participants a prescription drug manufactured by a Defendant Drug Manufacturer and identified in Appendix A.

AMCC at ¶ 595.

It is perfectly clear that nothing in the AMCC definition of the classes limited the classes to Part B covered drugs. *And Count I of the AMCC was on behalf of the AWP payor class, which again was not limited to Part B covered drugs.* And the allegations of Count I do not limit themselves to Part B drugs, but cover all AWPID drugs. *See, e.g., AMCC ¶¶ 624, 628(a), 638.* The only reference to Part B in all of Count I is in the heading (of the unmodified version), which as plaintiffs explained in the Notice, was a typographical error. Rather than inquire of plaintiffs' counsel of this discrepancy, which was surely noticed by the hundreds of defense lawyers working on this case, defendants persist in using this error as the basis for their standing argument as to Count I.

During the oral argument, not only was standing as to Count I raised for the first time, but defendants claimed for the first time that "Count I deals only with Medicare Part B." Tr. at 43. Plaintiffs' counsel were baffled by this argument and requested time to "think about it." Tr. at 54. Plaintiffs' counsel then discovered that the argument was predicated on an error in the heading of Count I that carried from the MCC, though as stated above, the actual charging allegations made it clear that Count I covered all AWP inflated drugs identified in Appendix A purchased outside of the PBM context. This typographical error was corrected in the modified complaint and is no longer operative.

The AMCC, Counts I and II thus focus on two different segments of the market. Count I covers all AWP inflated drugs in the AMCC that were purchased outside the PBM context. Count II covers all AWP inflated drugs purchased through the four identified PBMs.

The MCC was filed on September 6, 2002. In it, plaintiffs identified the PBM enterprises. Although defendants vigorously asserted that there must be a purchaser for each drug to have standing, they did not make a similar argument, with respect to the PBMs, namely that plaintiffs had

to have dealt through each PBM. The AMCC was filed on June 12, 2003. Again, defendants argued standing as to the purchaser of a specific drug, but not as to the PBMs, *i.e.*, that a plaintiff must have dealt with each PBM enterprise. There is a reason they waited to do so. Plaintiffs could easily satisfy this requirement, if it exists under the law, by adding plaintiffs to cover all PBMs if given notice that this was an issue.

As to standing on the actual claim as presented, several of the plaintiffs allege that their purchasers were based on inflated AWP. *See, e.g.*, ¶ 28 (typical reimbursement is at AWP – 10%); ¶ 29 (plaintiff “UFCW made payments for drugs outside of the Medicare Part B context based on published AWP”); ¶ 33 (plaintiff purchased Lipitor in whole or in part based on AWP).

III. ARGUMENT

A. Plaintiffs Have Standing for the Count I and Count IV Claims

Defendants claim that “the AMCC must be dismissed to the extent it seeks to bring Medicare Part B claims beyond the drug for which UFCW made Medicare Part B co-payments.” Defs. Mem. at 5.¹ Thus, defendants seek dismissal of portions of the claims in Count I and Count IV.

Defendants’ argument is predicated on the notion that Count I is limited to Part B covered drugs, which it is clearly not as explained above and as corrected by the modified complaint. Thus, because defendants’ argument is completely predicated on an error in the heading of Count I, which the modified complaint corrects, it is deficient. And defendants do not contest that plaintiffs purchased non Part B covered drugs. And as to Count IV, there was and continues to be *no* basis to suggest that those claims are limited to Part B covered drugs.

¹ Defendants completely ignore the allegations that certain individuals purchased Part B covered drugs. *See, e.g.*, ¶¶ 32, 34, 35.

B. Plaintiffs Have Standing on the PBM Claims

Based on what they call “minimal discovery,” defendants attack plaintiffs’ standing and claim “plaintiffs still do not allege that they contracted with any of the PBMs.” But if one looks at the allegations, the funds allege that they used the services of a PBM and that the reimbursement for drugs was tied to AWP, for example, “AWP-16%” and for mail order drugs, “AWP-23.” *See, e.g.*, ¶ 31. This allegation, repeated for each of the funds, complies with the Court’s Order that plaintiffs identify if the funds contracted based upon AWP:

The Court: Let me ask you. Is it true that each one of the plaintiffs contracted based upon AWP?

Mr. Berman: To the best of my knowledge that is true....

Tr. at 51.

The Court then ordered plaintiffs to allege this, (Tr. at 52), and return to this issue at the end of the hearing:

The Court: If, in fact, you know – if, in fact, these companies did contract based on either orally or in writing – assuming it’s in writing, they’re big companies – based on AWP and were injured thereby, I don’t know that you have to allege every transaction. In fact, you don’t under the cases I’ve dealt with before, but just allege it because you’ve alleged in general they’ve been prejudiced in reliance on AWP. So you say you’ve got it, do it. Week after Thanksgiving.

Tr. at 119.

And this was what defendants argued was missing from the AMCC: “On the PBM counts they don’t even allege they had a contract with a PBM.” Tr. at 47. Plaintiffs have now alleged precisely what defendants demanded.² Now, realizing that plaintiffs met this demand defendants

² *See, e.g.*, CMHV alleges that its administrator contracted directly with a PBM and that “all of CMHV’s drug purchasers were expressly tied to AWP.” ¶ 26. Plaintiff “UFCW has contracted with a PBM to administer the drug

once again up their demands, after argument and briefing, to demand that (a) each PBM must be identified in the plaintiff allegations, and (b) if plaintiffs did not contract with any PBM, then there is no standing as to this PBM and any transactions by class members as to that PBM. This new and after-the-fact argument should be rejected at this stage, having been raised, as is becoming a pattern with defendants, after plaintiffs responded to defendants attacks. And certainly the standing arguments cannot be based upon “minimal discovery,” but should be based upon the allegations of the complaint.

Indeed, the prematurity and improper nature of defendants’ argument is also revealed by the relief requested: “all claims in the AMCC related to payments through PBMs except for drugs on which PFT and Man-U made payments based on AWP pursuant to contracts with Express Scripts.” Defs. Mem. at 10. Defendants have received some discovery on these two defendants and hence based their arguments on this “minimal discovery,” while ignoring the allegations as to other plaintiffs. For example, plaintiff Board of Trustees of Carpenters and Millwrights of Houston and Vicinity Welfare Trust Fund (“CMHV”) alleges that its administrator contracted on CMHV’s behalf with a PBM and “by contract, all of CMHV’s drug purchases were directly and expressly tied to AWP.” ¶ 26. Discovery will show that this PBM was not Express Scripts, again demonstrating both the inaccuracy and premature nature of defendants’ motion. Defendants’ requested relief also ignores the allegations of United Food Commercial Workers Unions and Employers Midwest Health Benefits Fund (“UFCW”) that UFCW “has contracted with a PBM to administer the drug program for its members ... and that its contract” expressly provides that reimbursement is at “AWP less

program for its members” at “AWP less 13%. ¶ 29. Plaintiff PITH “used a PBM to provide prescription services” and at “all times its payment formula ... was expressly tied to AWP.” ¶ 30.

13%.” ¶ 29. Defendants do not explain why they ignore these allegations as well or why UFCW lacks standing.³

Further, defendants’ argument that plaintiffs must have contracted with each of the four PBMs to have RICO standing misconstrues the allegations of the AMCC. The AMCC *does not* seek as damages return of the specific inducements arranged between a particular drug manufacturer and a particular PBM (which inducements ought to have been passed to the specific PBM’s plan sponsors). Instead, the AMCC alleges that the RICO violations directly result in inflated AWP*s for all* AWP-based end-purchasers or reimbursers, regardless whether those class members had a specific relationship with a specific PBM. The AMCC alleges that:

654. *Each manufacturer-PBM enterprise had a common purpose of perpetuating use of AWPs as a benchmark for reimbursement in the pharmaceutical industry. The manufacturing defendants had this as a purpose, because without the use of inflated AWPs as an industry price setting benchmark, they would not be able to push the spread to those in the distribution chain.* The PBMs share this common purpose, because they are subject to a great deal of control from the manufacturers. PBMs are now turning to drug manufacturers for hidden profit-making schemes, because PBM clients are no longer allowing PBMs to collect as much for claims administration. Thus, as a result, PBMs have, with the knowing and willful participation and assistance of the drug manufacturers, engaged in hidden profit-making schemes falling into three general categories: (i) garnering rebates and other “soft dollars” from drug manufacturers that the PBM Defendants, to a large extent, keep without disclosing to their health plans the true amounts of the rebates; (ii) pocketing secret spreads between actual drug costs and the prices charged to health plans and their members; and (iii) keeping secret discounts provided by the drug manufacturers in association with the PBMs’ mail order operations. [¶ 654.]

And the AMCC alleges that all the PBMs were aware of and willing participants in the scheme:

³ Similar allegations as to plaintiff PITH are also ignored. ¶ 30.

660. At all relevant times, each one of the PBMs was aware of the Defendants Drug Manufacturers' AWP Scheme, was a knowing and willing participant in that scheme, and reaped profits from that scheme. [¶ 660.]

Indeed, this Court has already, and accurately, made this characterization of the AMCC:

Plaintiff union and employee health benefit plans contract with drug plan managers, known as Pharmacy Benefit Managers ("PBMs"), which operate as intermediaries between the pharmaceutical companies and the private health plans. These PBMs set prices on their formularies – their drug fee lists – based on the AWP figures reported in the same trade publications used by the Medicare program, less a certain percentage discount. Again, defendants market the same pricing and reporting "spread" to PBMs that they do to individual health care providers serving Medicare patients. The PBMs are offered drugs at highly "discounted" actual prices while charging the private health plans fees based on the inflated AWPs. The PBMs benefit by keeping the "spread" for themselves and the pharmaceutical companies benefit because PBMs are drawn to keeping on their formularies drugs from those companies offering the most lucrative "spreads."

In re Pharm. Indus. Average Wholesale Price Litig., 263 F. Supp. 2d 172,179-80 (D. Mass. 2003).

The AMCC alleges that the PBM RICO violations inflate the national AWP for drugs, and that therefore all class members who purchase or reimburse on the basis of the AWP are directly harmed. *See, e.g.*, ¶¶ 654, 671, 672. The ***motivation*** as to why drug manufacturers do this with PBMs (*i.e.*, that manufacturers either reluctantly acquiesce or actively court a PBM relationship to push or maintain market share through inflated AWPs capable of PBM exploitation) explains the economic basis for the relationship, but it does not delimit the legal claims of all AWP-based end-purchasers or reimbursers.

Nothing more is required to allege RICO causation or standing. RICO standing is not dependent on a contract between a PBM and a plaintiff; the issue on standing is whether plaintiffs have alleged that each of the PBM enterprises is a cause of their injury. RICO grants standing to

“any persons injured in his business or property.” 18 U.S.C. § 1962. Standing is satisfied if the RICO acts are the proximate cause of the injury. As Judge Wolf noted in *Sebago v. Bearer*, 18 F. Supp. 2d 70 (D. Mass. 1998), RICO is to be construed broadly and as for standing issues “it is for the jury to apply the law of proximate causation and ... decide whether the defendants were a substantial factor in causing plaintiffs’ harm.” *Id.* at 84.

A proximate cause of plaintiffs’ injury was the creation and use of inflated AWP’s as a benchmark. Each PBM enterprise contributed to the creation of inflated AWP’s as a benchmark, even if a plaintiff did not contract with that PBM. This satisfies the proximate cause test and hence RICO’s standing requirement. And this makes sense. Without the participation of any one of the four major PBMs, the scheme would have collapsed as payors would have had a dramatically less expensive alternative. Thus, a direct contract with a particular PBM is not a predicate to standing.

IV. CONCLUSION

Defendants’ motion is the latest in a continuing effort to raise new issues on a complaint that is, after all, a starting point in litigation. After each round of motions, and now even during oral argument and after oral argument, fearing that plaintiffs have met their latest demands, defendants manufacture new ones. The Court should halt this after the fact practice of imposing new and increasing pleading requirements. If one added up all of the demands made by defendants (prices paid for each drug, spreads, examples of gifts, grants, rebates for each drugs, a plaintiff-PBM relationship for each drug, etc.), this complaint would be thousands of pages and the alleged pleading requirements would be never ending.

Defendants claim that there latest attack on the complaint stems from confusion “that can occur when plaintiffs strive to bring a case that is as big as possible.” Defs. Mem. at Conclusion. As

noted during argument, plaintiffs carefully pared back the number of drugs at issue. The case remains “big” not due to plaintiffs’ efforts, rather its size is necessitated by the grandiose nature of defendants’ scheme. It is beyond doubt, from documents cited in the AMCC and the Congressional investigations cited as well, that AWP is an industry created benchmark and that AWP inflation effects hundreds of drugs. The size of the case stems from defendants’ greed, not plaintiffs’ complaint.

The current attack must, therefore, be rejected: (a) as to Counts I and IV, it is predicated on a typo; (b) as to Count IV, is simply fabricated; (c) as to Count II it ignores the complaint’s allegations and replaces them with arguments based on “minimal discovery,” and (d) as to Count II it is wrong as a matter of the law on RICO standing.

By Steve W. Berman signature on file

DATED: January 9, 2004.

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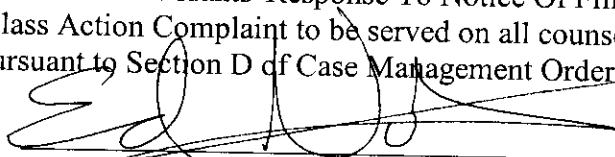
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CERTIFICATE OF SERVICE

I hereby certify that I, Edward Notargiacomo, an attorney, caused a true and correct copy of the foregoing Reply Memorandum In Response To Defendants' Response To Notice Of Filing Of Modified Amended Master Consolidated Class Action Complaint to be served on all counsel of record electronically on January 9, 2004, pursuant to Section D of Case Management Order No. 2.



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January 9, 2004

VIA HAND DELIVERY

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United States District Court
District of Massachusetts
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Re: In Re: Pharmaceutical Industry Average Wholesale Price Litigation
MDL No. 1456

Dear Sir/Madam:

Enclosed for filing in the above-captioned matter please find the following document:

1. Reply Memorandum In Response to Defendants' Response to Notice of Filing of Modified Amended Master Consolidated Class Action Complaint.

Please acknowledge this filing by date-stamping the enclosed copy of this letter and returning it to the waiting messenger.

Thank you.

Very truly yours ,

A handwritten signature in black ink, appearing to be "E. Notargiacomo", written over a horizontal line.

Edward Notargiacomo

Enclosure

cc: All counsel of record (Via VeriLaw)

EN:hcm